PATENT

Rev 09/03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application	:	Michael J. Evelegh
Application No.	:	09/830,708
Filed	:	April 30, 2001
Confirmation No.	:	3616
For	:	SPECTROPHOTOMETRIC MEASUREMENT IN COLOR-BASED BIOCHEMICAL AND IMMUNOLOGICAL ASSAYS
Examiner	:	Ralph Gitomer
Attorney's Docket	:	RDMA-002XX

TC Art Unit: 1651

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I hereby certify that this correspondence is being sent via facsimile to Examiner Ralph Gitomer, TC Art Unit 1651, Fax No. (703) 872-9306, on 12-22-3.

By: [signature]
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DECLARATION OF MICHAEL J. EVELEGH, PH.D. UNDER 37 C.F.R. §1.132

I, Michael J. Evelegh, a citizen of Canada, residing at 5 Parkway Place, Dundas, Ontario, Canada, declare the following:

1. I received my B.Sc. in Biology at Laurentian University, Ontario, Canada, a Ph.D. in Immunology from McMaster University in Ontario, Canada, and was a Post-Doctoral Fellow at the National

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Cancer Institute in McMaster University, Ontario, Canada. Currently, I am an Executive Vice-President for IMI International Medical Innovations, Inc., located at 4211 Yonge Street, Suite 300, Toronto, Ontario, Canada, M2P 2A9, which is in the business of developing innovative tests that detect life-threatening diseases at the earliest possible stage, currently being focused on cardiovascular diseases and cancer.

2. I have extensive technical and research experience in the areas of developing *in vitro* diagnostics for infectious diseases, heart disease, and cancer from the discovery process through to product development. My research was focused on novel assays based on color change and measurement. I have authored over 40 peer-reviewed scientific papers, posters and podium presentations at scientific meetings and invited talks.

3. I am an inventor of the subject matter described and claimed in the above-identified patent application.

4. I have read and am familiar with the prosecution history of the present application, including the outstanding final Office Action dated August 4, 2003 (Paper No. 10).

5. The Detailed Action in the Office Action, starting on page 2, states that the rejection for claims 1 and 8 are maintained as being anticipated by Lee et al. (PCT WO 90/00251), and, in part, by Shamsuddin and Krepinsky. The Examiner asserts, with regard to Lee et al., that "the present claims are not based on absolute color, they are based on "spectrophotometrically

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measuring hue angle or chroma" which reads on most types of standard spectrophotometric determinations including wavelength change or reflectance." In addition, starting on page 3, the Detailed Action alleges that various claim sets are rejected as being unpatentable and obvious over cited references in which the Lee et al. reference is contemplated in all sets of rejections in combination with other secondary references.

6. I respectfully disagree that Lee et al., Shamsuddin and/or Krepinsky render the application unpatentable. The cited references fail to anticipate each and every element of the invention as claimed and also fail, either alone or in combination with each other, to teach or suggest the claimed invention.

7. One of ordinary person skilled in the art would understand that there are fundamental, patentable distinctions between the present application and Lee et al.

8. Chromaticity is defined as "the intensity or saturation level of a particular hue, defined as the distance of departure of a chromatic value from the neutral (gray) color with the same value." (*A Guide to Understanding Color Communication*. X-Rite, Inc., 2000, p. 22 (Exhibit A).) Hue is defined as the attribute by which we distinguish red from green, blue from yellow, etc. (*Id.*, p. 24) There are five principal hues (red, yellow, green, blue and purple) and five intermediate hues (yellow-red, green-yellow, blue-green, purple-blue and red-purple). (*Ibid.*) Hue is determined by measuring the entire visible spectrum, which is generally between infrared light (approximately 700nm wavelength)

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and ultraviolet light (approximately 400nm wavelength). Chroma can be thought of as the amount of identifiable hue that is present in a color. ("Color Theory," www.colorcube.com/articles/theory/theory.htm [accessed November 17, 2003] (Exhibit B).) As claimed, the value obtained from the measurement of the hue angle with or without chroma in a biological material is spectrophotometrically measured and electronically processed over a wide spectrum.

9. The process described and claimed in the present application involves an electronic measurement of color with a reflectance spectrophotometer and color measuring software to calculate the hue and chroma obtained by the chemical reactions sited. This objective measurement is a significant improvement over the subjective interpretation of color (e.g., using a color chart) since a color chart is strongly influenced by viewer variables and this creates significant variability due to viewer to viewer differences. Measuring color with the spectrophotometer, as described and claimed in the present application, can objectively identify chroma and hue with errors less than 1%.

10. In contrast to the present invention, Lee et al. refers to interpreting a positive test using a "color chart" or a "reflectance spectrophotometer" (*see* WO 90/00251, page 16, bottom paragraph). Lee et al. makes reference to color measurement in only one paragraph starting on the bottom of page 16 to top of page 17. Lee et al. refers to chromaticity but incorrectly suggests (as further explained below) that this term encompasses

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determining hue. Instead, Lee et al.'s claims focus on an apparatus and methods for assaying test substances such as microbes. Neither hue nor chroma are used by Lee et al. to define test results from biochemical reactions on biological samples as claimed in the present application.

11. The novel concept of applying these measures to these types of samples have not previously been considered by others.

12. Lee et al. states that, when the reflectance spectrophotometer was used, "a reading of 10 or above" (page 16, bottom paragraph) indicated a positive test. Lee et al. then goes on to state, "[w]hen the reflectance spectrophotometer was used the colorimetric data was calculated from the spectral data measured by the sensor. The total color difference (DE) was measured by the L, a, b coordinate system and was recorded in units." (Page 16, bottom paragraph.) I interpret this to mean that a DE of 10 or more indicated a positive test. DE is a single number that reflects the difference between two colors based on lightness/darkness, redness/greenness, and yellowness/blueness. ("Color Gamuts," http://cit.dixie.edu/vt/reading/gamuts.asp [accessed November 17, 2003] (Exhibit C).) This value does not represent both chromaticity and hue even though Lee et al. seems to indicate such - "chromaticity difference (chromaticity and hue)." In fact, DE "is a single number indicating the total or collective color difference between standard and sample. It describes the magnitude of a color difference, but does not indicate in any way in what direction those differences may be." ("Color Difference Measurements,"

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http://www.gecolorxpress.com/jsp/extranet/user/start/quantifying6.jsp [accessed November 17, 2003] (Exhibit D).) Lee et al. seems to misunderstand this concept as he states - "the higher the value of DE, the more saturated and chromatic was the color" (page 17, beginning paragraph). Furthermore, even though Lee et al. is measuring a color difference, he does not identify the corresponding reference color. In addition, by looking at the collective color difference, Lee et al. neglects the key specific information associated with hue and chroma. It is apparent that Lee et al. does not apply color measurement nor does he teach or suggest the specifics of color in technical detail as in the present invention.

13. Shamsuddin and Krepinsky simply report measuring wavelength at a single or narrow range of wavelengths. Neither hue nor chroma can be determined from this measurement and indeed their technique is not novel as it is well established as a method.

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I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the Unites States Code, and that such willful false statements so made may jeopardize the validity of the document, or application, or any patent issuing thereon.

Signed this 22 day of December, 2003.

By: ______________________
Michael J. Evelegh, Ph.D.

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